JUL 2 6 2013

510(k) SUMMARY: SUSTAIN® and SUSTAIN® Radiolucent Spacers

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Christina Kichula
Group Manager, Regulatory Affairs

Date Prepared: February 22, 2013

Device Name: SUSTAIN® and SUSTAIN® Radiolucent (SUSTAIN® R) Spacers

Classification: Per 21 CFR as follow:
§888.3060 Implant, fixation, spinal intervertebral body fixation orthosis devices
§888.3080 Intervertebral Body Fusion device
Product Codes MQP, MAX, and ODP.
Regulatory Class II, Panel Code 87.

Predicate(s):
PATRIOT® Spacers (Lumbar) K072970
PATRIOT® Spacers (Cervical) K072991
PATRIOT® Transcontinental™ Spacers (Lumbar) K093242
CALIBER™ Spacers (Lumbar) K102293
SUSTAIN® Spacers K031302
SUSTAIN® Radiolucent Spacers K040284
COALITION® Spacers K083389
BAK/Cervical (BAK-C®) Interbody Fusion System P980048

Purpose:
The purpose of this submission is to add intervertebral indications for SUSTAIN® and SUSTAIN® R Spacers and to make sterile spacers available.

Device Description:
SUSTAIN® and SUSTAIN® R Spacers are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. These spacers are available in different shapes and heights to accommodate various surgical approaches and anatomical needs. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

These spacers are used to provide structural stability in skeletally mature individuals following discectomy, corpectomy, or vertebrectomy (including

partial). Lumbar spacers may be inserted using a posterior, transforaminal, anterior, anterolateral, or lateral lumbar approach. Cervical spacers are inserted using an anterior cervical approach.

The SUSTAIN® Spacers are made from commercially pure titanium or titanium alloy as specified in ASTM F67, F136, and F1295.

The SUSTAIN® R Spacers are made from radiolucent peek polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026.

Indications for Use
When used as lumbar intervertebral body fusion devices, SUSTAIN® and SUSTAIN® Radiolucent (SUSTAIN® R) Spacers are intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE®, REVOLVE™ or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, the SUSTAIN® and SUSTAIN® R Spacers are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE® or XTEND® Anterior Cervical Plate System.

When used as vertebral body replacement devices, SUSTAIN® and SUSTAIN® R Spacers are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. SUSTAIN® and SUSTAIN® R Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Performance Data
Mechanical testing (static and dynamic compression, static and dynamic torsion, static and dynamic compression shear, and subsidence) was conducted in

accordance with the "Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device," June 12, 2007. Performance and comparative analysis data demonstrate substantial equivalence to the predicate devices.

Basis for Substantial Equivalence:
SUSTAIN® and SUSTAIN® R Spacers are identical to the predicate SUSTAIN® and SUSTAIN® R Spacers with respect to design, technical characteristics, performance and vertebral body replacement indications for use. SUSTAIN® and SUSTAIN® R Spacers are equivalent to the predicate PATRIOT® Spacers with respect to intervertebral body fusion devices indications for use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. SUSTAIN® and SUSTAIN® R Spacers are as safe, as effective, and perform as well as or better than predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Globus Medical Incorporated
% Ms. Christina Kichula
Group Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K130478
Trade/Device Name: SUSTAIN® and SUSTAIN® Radiolucent Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: June 25, 2013
Received: June 26, 2013

Dear Ms. Kichula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K130478

Device Name: SUSTAIN® and SUSTAIN® Radiolucent Spacers

INDICATIONS

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When used as a cervical intervertebral body fusion device, the SUSTAIN® and SUSTAIN® R Spacers are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The SUSTAIN® and SUSTAIN® R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE® or XTEND® Anterior Cervical Plate System.

When used as a vertebral body replacement device, SUSTAIN® and SUSTAIN® R Spacers are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. SUSTAIN® and SUSTAIN® R Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Prescription Use ___X___ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices